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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,334	08/03/2006	Craig Johnstone	056291-5298	7217

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MORGAN LEWIS & BOCKIUS LLP  
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WASHINGTON, DC 20004

EXAMINER
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ZAREK, PAUL E

ART UNIT	PAPER NUMBER
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1628

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10/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,334	<b>Applicant(s)</b> JOHNSTONE ET AL.	
	<b>Examiner</b> Paul Zarek	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 18-21, 26-29 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22, 24, 25 and 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 18-22, 25-33, and 35 have been amended and Claim 23 has been cancelled by the Applicant in correspondence filed on 06/29/2009. Claims 18-22 and 25-35 are currently pending. Claims 22, 24, 25, and 30-32 read on the elected invention and species and are examined herein. Claims 18-21 remain withdrawn as being drawn to a nonelected species. Claims 33-35 remain withdrawn as being drawn to a nonelected invention. This is the second Office Action on the merits of the claim(s).

## **RESPONSE TO ARGUMENTS**

2. Examiner acknowledges Applicants' amendment to the specification to properly claim the benefit of prior-filed international application no. PCT/GB05/00545. The effective filing date of the instant application is 02/12/2005. By perfecting the claim for the benefit of the international application, Applicants have also perfected the claim to foreign priority. The date of foreign of the instant application is 02/18/2004.
3. Claims 22, 23, and 30-32 were objected to because R<sup>4</sup> listed HET-2 twice. This objection is moot in light of Applicants' amendment to Claim 22 and cancellation of Claim 23.
4. Claims 22-25 and 30-32 were rejected under 35 U.S.C. 112, first paragraph, for not being enabled for solvates and prodrugs of the compounds of formula (I). With respect to Claims 23, 24, 25, and 30-32, this rejection is moot due to amendment or cancellation of the Claims. Applicants have not deleted "solvate" and "pro-drug" from Claim 22. Therefore, the rejection of Claim 22 under 35 U.S.C. 112, first paragraph, is maintained.

Art Unit: 1617

5. Claims 22, 23, and 30-32 were rejected under 35 U.S.C. 112, first paragraph, for not being enabled for R<sup>6</sup> to be HET-4. This rejection is moot in light of Applicants' amendment to Claim 22 and cancellation of Claim 23.

6. Claims 22 and 30-32 were rejected under 35 U.S.C. 112, first paragraph, for not being enable for HET-2 and HET-3 to comprise substituents other than a C<sub>4</sub>-C<sub>6</sub> cycloalkyl or heterocycloalkyl substituted with up to 2 heteroatoms of nitrogen, oxygen, and sulfur. This rejection is moot in light of Applicants' amendment to Claim 22.

7. Claims 22 and 30-32 were rejected under 35 U.S.C. 112, second paragraph, because "optionally substituted" was unclear. This rejection is moot in light of Applicants' amendment to Claim 22.

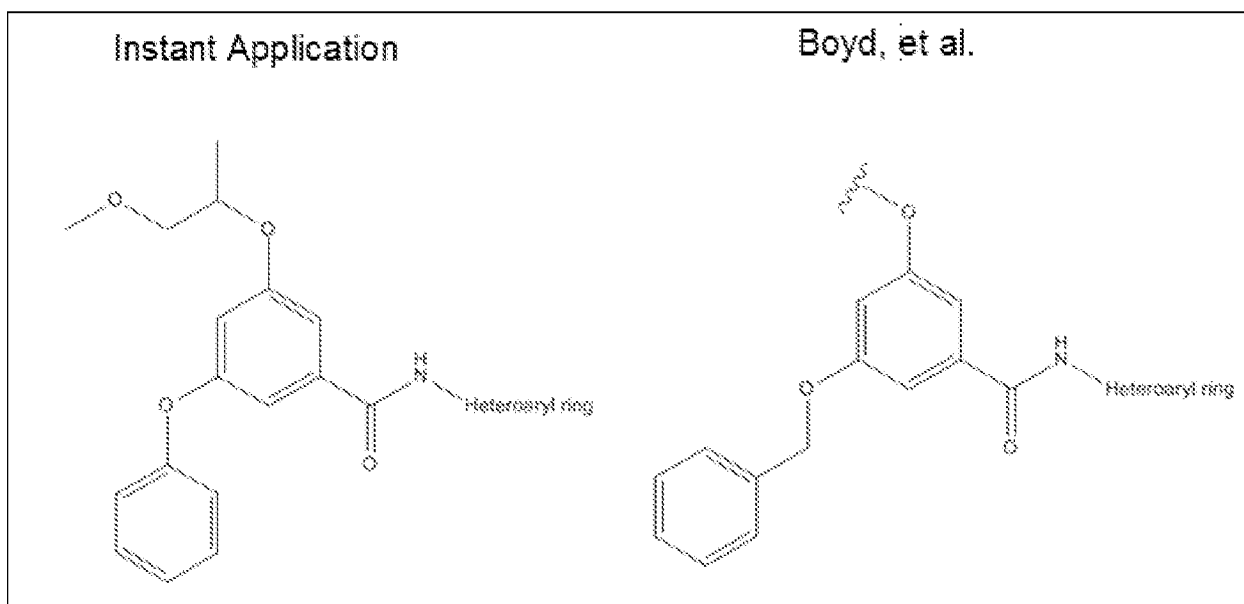
8. Claims 22 and 30-32 were rejected under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for various substituents. This rejection is moot in light of Applicants' amendment to Claim 22.

9. Claims 22-25 and 30-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd, et al. (International Application No. WO 03/015774, provided in IDS). Examiner notes that Claim 23 has been cancelled, thus this rejection no longer applies to Claim 23. Applicants traversed this rejection on the grounds that Boyd, et al., does not teach or fairly suggest the claimed invention. Specifically, Applicants assert that the compounds disclosed in Boyd, et al., lack the mandatory methoxy-(1-methyl)ethoxy group at the 3-position and the mandatory phenoxy group para-substituted by HET3-CO or HET3-SO<sub>2</sub>. Moreover, Applicants contend that Boyd, et al., provides no motivation for the skilled artisan to modify the compounds contained

Art Unit: 1617

therein. Applicants cite *In re Baird* in support of their arguments. Respectfully, Examiner does not find Applicants' argument persuasive.

10. Boyd, et al., teach numerous glucokinase activating agents (abstract), and pharmaceutical compositions thereof (pg 1, line 8) with a structure similar but not identical to instantly claimed Formula (I). Examiner notes that both Boyd, et al., and the instantly claimed compounds contain a very similar core, differing in that Boyd, et al., teach a benzyloxy substituent at the 5-position rather than the instantly claimed phenoxy substituent, and that Boyd, et al., do not disclose a (1S)-methoxy-(1-methylethyl)oxy group as R<sup>1</sup> at the 3-position.



11. R<sup>3</sup> in Boyd, et al., corresponding to HET1 of the instant invention (both indicated by “Heteroaryl ring” in the above cartoon), can be either pyrazole (Table GG, pg 90) or thiazole (Table II, pg 96). Both pyrazole and thiazole are encompassed by HET1. Examples GG 2-4, 6, and 7 disclose a 1-methyl group on the pyrazole. Examples II 100, 107, and 108 teach a 1-methyl group on the thiazole.

Art Unit: 1617

12. Boyd, et al., disclose various moieties that are encompassed by R<sup>1</sup> and the 3-position of the central phenyl ring. These include substituted benzyloxy, 2-methylpropyloxy, and 1-methylethyloxy. There is also a variety of substituents at the 5-position of the central phenyl ring. All of the compounds disclosed by Boyd, et al., are taught as glucokinase activating agents (abstract). The instantly claimed compounds recite the same utility (glucokinase activating agents (instant abstract) and retain the same core. It is within the purview of the ordinarily skilled artisan to modify the compounds disclosed in Boyd, et al., to achieve superior glucokinase activating agents. *In re Baird* states that “The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.” (MPEP § 2144.08(II)) Examiner is not using only the fact that the core disclosed in Boyd, et al., and the instant invention are exceedingly similar, Examiner also notes that the compounds taught by Boyd, et al., and the instantly claimed compounds recite the same utility.

13. Applicants acknowledge such similarity between the instantly claimed compounds and those of the prior art by stating that the instantly claimed compounds are “a selected subgroup of those described in [Boyd, et al.]” which possess “more advantageous physical properties” (pg 3, lines 27-30). Examiner interprets the disclosed physical properties to indicate enhanced bioavailability. Applicants’ disclosure of a single compound (Example 11b) possessing enhanced bioavailable is not sufficient to generally state that all or a significant portion of the claimed invention would also have unexpectedly higher bioavailability. “Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the ‘objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.’ In other words, the showing of unexpected

Art Unit: 1617

results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980)” (MPEP § 716.02 (d)). In the present instance, Applicants have not demonstrated unexpectedly enhanced bioavailability of a sufficient number of compounds commensurate with the scope of the claims. For these reasons, the rejection of Claims 22, 24, 25 and 30-32 under 35 U.S.C. 103(a) as being unpatentable over Boyd, et al., is maintained.

14. Applicants can overcome this rejection by demonstrating, in a side-by-side comparison, the unexpectedly superior properties of the instantly claimed invention.

15. Claims 22, 23, and 30-32 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22, and 30 of copending Application No. 11/665,222. This rejection is moot in light of the abandonment of the Application No. 11/665,222.

16. Claims 22, 23, and 30-32 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 and 30 of copending Application No. 11/665,163. Applicants have not disagreed with this rejection, instead pointing out that if a provisional nonstatutory obviousness-type double patenting rejection is the sole rejection remaining, it is to be withdrawn from the earlier filed (e.g. the instant) application. This rejection is maintained because the nonstatutory obviousness-type double patenting is not the sole remaining rejection.

### ***Conclusion***

17. Claims 22, 24, 25, and 30-32 remain rejected.

Art Unit: 1617

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brendon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/  
Primary Examiner, Art Unit 1628